Filing Date: May 10, 2001

Title: METHOD AND DEVICE FOR PREVENTING PLAQUE FORMATION IN CORONARY ARTERIES

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## **REMARKS**

In response to the Office Action mailed on September 8, 2003, claims 1 and 10 are amended; as a result, claims 1-25 are now pending in this application. Claims 21-25 stand withdrawn.

## §103 Rejection of the Claims

Claims 1-3, 6-8, 10-14, 16, 17, and 19 were rejected under 35 USC § 103(a) as being unpatentable over Chekanov (U.S. Patent No. 6,201,991, "Chekanov") in view of Dev et al., (U.S. Patent No. 6,347,247, "Dev") and further in view of Eggers et al., (U.S. Patent No. 4,998,933, "Eggers").

Regarding claim 1:

Claim 1 was amended to better recite the subject matter. Support for the amendment is found generally throughout the specification. *See, e.g.*, page 7 lines 9-13. If the rejection is applied to the amended claim, Applicant respectfully traverses the rejection. To establish prima facie obviousness of a claimed invention, all the claim limitations must be taught or suggested by the prior art. M.P.E.P. § 2143.03.

Applicant is unable to find in the cited portions of the proposed combination of references, among other things,

generating an electrical field, ..., and wherein generating the electrical field includes outputting a non-excitatory electrical field in association with an atrial or ventricular depolarization such that the electrical field does not interfere with the heart rhythm,

as recited in claim 1. In contrast, Eggers describes use of a high frequency current to minimize the risk of interfering with the natural pacing of the heart (*See* Eggers col. 3 lines 36-45). Thus, the proposed of combination of Eggers with Chekanov and Dev does not discuss generating a field in association with a depolarization.

Applicant respectfully requests reconsideration and allowance of claim 1.

Regarding claims 2-3, 6-8:

Applicant traverses the rejection. Claims 2-3 and 6-8 ultimately depend on claim 1. The claims are believed to be allowable at least for the reasons stated previously for claim 1.

Further, Applicant can not find where Dev teaches or suggests using electric fields to prevent plaque build-up. Dev teaches a device that dilates a vessel, and discusses denuding of

cells that comprise a blood vessel that is independent of the applied electrical parameters. See Dev, col. 6 lines 42-63. Because the blood vessel is not comprised of the plaque, the cited portions of Dev do not discuss preventing plaque build-up in an artery. Also, because the denuding is not related to the electrical parameters, the cited portions of Dev do not discuss preventing plaque build-up in an artery using an electric field. Accordingly, there is no motivation to combine Dev with Chekanov.

Applicant respectfully requests reconsideration and allowance of claims 2-3 and 6-8.

Regarding claims 10-14, 16, 17, 19:

Claim 10 was amended to better recite the subject matter. Support for the amendment is found generally throughout the specification. *See, e.g.*, page 7 lines 9-13. If the rejection is applied to the amended claim, Applicant respectfully traverses the rejection.

Applicant is unable to find, among other things, where the electrical field generating device produces an electrical field in association with an atrial or ventricular depolarization that does not interfere with the heart rhythm, as recited in claim 10.

Claims 11-14, 16, 17 and 19 ultimately depend on claim 10 and are believed to be allowable at least for the reasons stated above for claim 10.

Applicant respectfully requests reconsideration and allowance of claims 10-14, 16, 17 and 19.

Claims 4, 5, 18, and 20 were rejected under 35 USC § 103(a) as being unpatentable over Chekanov (U.S. Patent No. 6,201,991) in view of Dev et al., (U.S. Patent No. 6,347,247) and further in view of Eggers et al., (U.S. Patent No. 4,998,933) and further in view of Halsuka et al., (U.S. Patent No. 4,830,006, "Halsuka").

Applicant traverses the rejection. Claims 4 and 5 ultimately depend on base claim 1, and claims 18 and 20 depend on base claim 10. Applicant believes the claims to be allowable at least for the reasons stated for the base claims, namely claims 1 and 10. Applicant respectfully requests reconsideration and allowance of claims 4, 5, 18 and 20.

Claims 9 and 15 were rejected under 35 USC § 103(a) as being unpatentable over Chekanov (U.S. Patent No. 6,201,991) in view of Eggers et al., (U.S. Patent No. 4,998,933) and further in view of Haluska et al., (U.S. Patent No. 4,830,006).

AMENDMENT AND RESPONSE UNDER 37 CFR § 1.111

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Applicant respectfully traverses the rejection on the following three grounds:

First, Applicant is unable to find all of the elements recited in claims 9 and 15 in the cited portions of the proposed combination of Chekanov, Eggers and Halsuka. Applicant is unable to find in the proposed combination, among other things,

generating an electrical field in the coronary artery to prevent plaque build-up in the coronary artery, wherein generating the electrical field includes generating the electrical field during a refractory period at a higher strength and generating the electrical field during a non-refractory period at a lower strength, as recited in claim 9. Neither is Applicant able to find, among other things,

wherein the lead unit includes two leads ..., wherein one of the two leads is adaptable to be positioned in an anterior vein and a second of the two leads is adaptable to be positioned in a lateral vein, and the electrical field is a non-heart-excitatory signal passing through a left marginal artery and an anterior interventrical artery,

as recited in claim 15.

Second, the mere fact that the prior art could be modified to provide the subject matter of the claims is not sufficient to establish obviousness, there must be motivation (e.g., a teaching, a suggestion, an incentive) in the prior art to make such modification. See M.P.E.P. § 2143.01. Applicant respectfully submits that the Office Action fails to establish *prima facie* obviousness because the cited portions of the proposed combination does not provide a teaching, suggestion, or incentive to modify the prior art to provide the subject matter of the claims.

Third, obviousness to try a modification represents an insufficient basis to modify or combine references. For *prima facie* obviousness, the prior art must provide a reasonable expectation that the proposed modification will succeed. *See* M.P.E.P. § 2143.02. Although, obviousness does not require absolute predictability, a reasonable expectation of success is necessary. Because the cited portions of the proposed combination of references do not discuss modifications to arrive at the subject matter of claims 9 and 15, the proposed combination does not provide a reasonable expectation that the modifications will succeed.

Applicant respectfully requests reconsideration and allowance of claims 9 and 15.

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## **CONCLUSION**

Applicant respectfully submits that the claims are in condition for allowance and notification to that effect is earnestly requested. The Examiner is invited to telephone Applicant's attorney ((612) 349-9587) to facilitate prosecution of this application.

If necessary, please charge any additional fees or credit overpayment to Deposit Account No. 19-0743

Respectfully submitted,

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CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Commissioner of Patents, P.O. Box 1450, Alexandria, VA 22313-

1450, on this day of December, 2003.

Name

Signature